GUIDELINES ON SUBMISSION OF DOCUMENTATION FOR RENEWAL OF REGISTRATION OF A PHARMACEUTICAL PRODUCT FOR HUMAN USE

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These guidelines shall be cited as the *"Professional* Guidelines on *Submission of Documentation for Renewal of Registration of a Pharmaceutical product for human use., Doc. No. PAR/GDL/020, Revision No.: 0"*

Adoption and approval of these professional guidelines

In EXERCISE of the powers conferred upon the Drug Authority by Section 5(i) of the National Drug Policy and Authority Act, Cap. 206 of the Laws of Uganda (2000 Edition), the Drug Authority hereby ADOPTS and ISSUES these Professional Guidelines on **Submission of Documentation for Renewal of Registration of a Pharmaceutical product for human use**., Doc. No. PAR/GDL/020, Revision No.:0, made this 24th day of October, 2019, that take effect on 01st November 2019.

Signature

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1.0 INTRODUCTION

National Drug Authority (NDA) was established in 1993 by the National Drug Policy and Authority Statute which in 2000 became the National Drug Policy and Authority (NDP/A) Act, Cap. 206 of the Laws of Uganda (2000 Edition). The Act established a National Drug Policy and National Drug Authority to ensure the availability, at all times, of essential, efficacious and cost-effective drugs to the entire population of Uganda, as a means of providing satisfactory healthcare and safeguarding the appropriate use of drugs.

The Vision of NDA: *"A Uganda with safe, effective and quality medicines and healthcare products."*

The Mission of NDA: *"Promoting and protecting public health through the effective regulation of human and animal medicines and healthcare products". "The National Drug Policy and Authority Act, Section 35 mandates NDA to scientifically examine any drug for purposes of ascertaining efficacy, safety and quality of a drug before registration for use in Uganda.*

The National Drug Policy and Authority (Registration) Regulations SI No. 29 of 2014; Regulation 40.(1) states that:

The Authority shall issue for the first registration, a certificate of registration which shall be valid for five years.

It is acknowledged that in the course of five years several aspects of the registered medicinal product may change significantly as a result of notified variations and other un-notified changes in manufacturing and control of the products. These may have significant impact on the respective product and therefore, the objective of renewal of registration is to ensure that the product continues to conform to the above mentioned requirements.

The Common Technical Document (CTD) format which involves the assembling of all quality, safety and efficacy information in a common format called CTD has revolutionized the regulatory review processes and has led to harmonized electronic submission that in turn has enabled implementation of good review practices. These guidelines, which require use of the Common Technical Document (CTD) format shall be followed by all applicants when preparing applications for renewal of Marketing Authorization (**renewal of registration)** of Pharmaceutical Products for Human use intended for submission to NDA.

The main CTD guidelines document Doc. No.: PAR/GDL/004; (**Guidelines on Submission of Documentation for Marketing Authorization of a Pharmaceutical Product for Human Use)** should be referred to in preparation of the submission.

1.1 Objective of these guidelines

These guidelines are intended to provide guidance to applicants to prepare product dossiers for submission to NDA during renewal of registration of a Pharmaceutical Product for Human Use.

1.2 Policy

These guidelines are developed in accordance with the National Drug Policy and Authority Act Cap 206, Section 35(1)(a): "the drug authority may scientifically examine any drug for the purposes of ascertaining efficacy, safety and quality of that drug"

Section 35(3) "if, on application made in the prescribed manner and on payment of the prescribed fee, the Authority is satisfied that the drug or preparation in respect of which the application is made has not been registered; and that the use of the drug or preparation is likely to prove beneficial, the Authority shall register the name and description of that drug or preparation".

The National Drug Policy and Authority (Registration) Regulations SI No. 29 of 2014; Regulation 40.(1) states that:

"The Authority shall issue for the first registration, a certificate of registration which shall be valid for five years".

The National Drug Policy and Authority (Registration) Regulations, SI No. 29 of 2014; Regulation 4 states that;

"(1) All products shall be registered in Uganda before sale or distribution".

"(2) A person who intends to manufacture, import or export a product shall, prior to the manufacture, importation or exportation of the product, apply to the Authority for registration of the product".

The National Drug Policy and Authority (Registration) Regulations, 2014 ; Regulation 42(1) states that; *"A holder of a certificate of registration who wishes to renew the registration shall submit an application for renewal of registration, to the Authority at least 90 days before the expiry of the registration".*

1.3 Scope

These guidelines apply to product dossiers for human medicinal products containing existing APIs of synthetic or semi-synthetic origin, APIs of natural origins, vaccines, biosimilars, and Biotherapeutics.

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2.0 GLOSSARY

The definitions provided below apply to the words and phrases used in these guidelines. The following definitions are provided to facilitate interpretation of the guidelines.

Active pharmaceutical ingredient: A substance or compound that is intended to be used in the manufacture of a pharmaceutical product as a pharmacologically active compound (ingredient).

Agent (Local Technical Representative - LTR): Every applicant who is not resident in Uganda shall appoint a person in Uganda and authorized by NDA to deal in medicinal products to be an AGENT (Local Technical Representative (LTR). The appointment shall be notified to the Authority by submitting a letter of appointment supported by original copy of power of attorney. Dully notarised in country of origin and registered with the Uganda Registration Services Bureau.

Applicant: An applicant is a person (patent holder, licensed person, manufacturer or agent) who applies for registration of a medicinal product to NDA, who must be the owner of the product. He may be the manufacturer or a person to whose order and specifications, the product is manufactured. The applicant shall therefore be responsible for signing the registration application form. In the event that the applicant wants another person to register the medicinal product on his behalf, then Powers of Attorney, duly notarized in the country of origin, and registered with the the Uganda Registration Services Bureau shall be provided. After the product is registered, the applicant shall be the **Marketing Authorisation Holder (MAH).**

Authorized person: A person responsible for the release of batches of finished product for sale or distribution. The batch documentation of a batch of a finished product must be signed by an authorized person from the production department and the batch test results by an authorized person from the quality control department for batch release.

Authorized pharmacopoeia (or compendium): means the current edition for the time being of any of the following, namely, the International Pharmacopoeia, the

British Pharmacopoeia, the British Pharmaceutical Codex, the European Pharmacopoeia, the United States Pharmacopoeia and the British Veterinary Codex.

Drug: means any substance or preparation used or intended to be used for internal or external application to the human or animal body either in the treatment or prevention of disease or for improving physiological functions, or for agricultural or industrial purposes.

Generic product: A medicinal product which has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference medicinal product, and whose bioequivalence with the reference medicinal product has been demonstrated by appropriate bioavailability studies.

Innovator product: Generally the pharmaceutical product that was first authorized for marketing (normally as a patented product) on the basis of documentation of efficacy, safety and quality.

Manufacturer: A manufacturer is a natural or legal person with responsibility for manufacturing of a medicinal product or active pharmaceutical ingredient. It involves operations such as production, packaging, repackaging, labelling and relabeling of pharmaceuticals.

Marketing authorization (product license, certificate of registration): A legal document issued by the competent drug regulatory authority that establishes the detailed composition and formulation of the product and the pharmacopoeial or other recognized specifications of its ingredients and of the final product itself, and includes details of packaging, labeling and shelf-life.

Marketing Authorization Holder (MAH): Is the holder of the certificate of registration issued by the National Drug Authority.

Medicinal product, finished product or finished pharmaceutical product (FPP): A product that has undergone all stages of production, including packaging in its final container and labeling.

Packaging material: Any material, including printed material, employed in the packaging of a pharmaceutical product, excluding any outer packaging used for transportation or shipment. Packaging materials are referred to as primary or

secondary according to whether or not they are intended to be in direct contact with the product.

Pharmaceutical product: Any medicine intended for human use or veterinary product administered to food-producing animals, presented in its finished dosage form or as a starting material for use in such a dosage form, that is subject to control by pharmaceutical legislation in both the exporting state and the importing state.

3.0 PROCEDURE FOR SUBMISSION OF AN APPLICATION FOR RENEWAL OF REGISTRATION OF A PHARMACEUTICAL PRODUCT FOR HUMAN USE.

a) The responsibility of applying for product renewal of registration rests with the Marketing Authorization Holder (MAH);

b) The application should be typed in English. Any documents which are in any language other than English must be accompanied by a certified or notarized English translation.

c) The application must contain a complete index to the various appendices.

d) The summaries should be formatted as word document, and the body data in PDF format with bookmarks and optical character recognition (OCR) readable

e) All pages of the application should be numbered in the style: *page x of y.*

f) The application should be submitted in CD-ROM addressed to: The Secretary to the Authority, National Drug Authority.

g) A separate application is required for each product that is registered.

4.0 APPLICATION FOR RENEWAL OF REGISTRATION

A holder of a certificate of registration who wishes to renew the registration shall submit an application for renewal of registration, to the Authority at least 90 days before the expiry of the registration.

An application for renewal of registration shall be in writing to the Authority and shall be accompanied by—

a) a consolidated report of the changes, if any, whether reported to the Authority or not, which are made with respect to the registered drug or preparation, vaccine or other immunological products, as the case may be, during the validity of its registration;

b) a report of additional adverse drug reactions, if any, detected during the lifetime of the registered drug or preparation, vaccine or other immunological products or surgical instrument, as the case may be;

c) One sample of the registered drug or preparation, vaccine or other immunological products, as the case may be, for which renewal of registration is sought, in the form in which it is to be marketed;

d) Specimen of current package insert and copies of colored mock up labels of the product as per current requirements prescribed in section 1.5.4 and appendix 4 of the main Registration Guidelines for Human Pharmaceutical Products. *(A mock-up is a copy of the flat artwork design in full colour, presented so that, following cutting and folding where necessary, it provides a replica of both the outer and immediate packaging so that the three dimensional presentation of the labelling text is clear. This mock-up is generally referred to as a paper copy and not necessarily in the material of the sales presentation. A specimen is a sample of the actual printed out outer and immediate packaging materials and package leaflet (i.e. the sales presentation).*

e) All prescription medicines should be accompanied by SmPC. Refer Guidelines on Format and Content of Summary of Product Characteristics for Human Pharmaceutical Products.

f) All Pharmaceutical preparations with potential for long-term use must contain a patient information leaflet.

g) Submission of periodic post-marketing surveillance and safety studies for products indicated as per current requirements prescribed in section 1.13 Submission of risk management (RMP)

5.0 ADDITIONAL INFORMATION

a) Where the information or documents submitted in respect of an application for renewal of registration are not sufficient for the Authority to determine whether the product to be registered meets the quality, safety and efficacy requirements determined by the Authority, the Authority may request the applicant to submit additional information necessary for the renewal of registration. A letter to this effect will be sent to the applicant.

b) Additional information provided should be complete and accurate. If the information provided is insufficient as deemed by the Authority then more additional information shall be requested for. This, however, can only be done for a maximum of three times, after which if the information provided is still inadequate then the application for renewal of registration will be rejected. The applicant will have to re-apply for registration if he/she is still interested.

6.0 POST RENEWAL VARIATION TO PHARMACEUTICAL PRODUCTS

All variations to a registered pharmaceutical product shall be made according to requirements stipulated in the Application Guidelines for Variation of Registered Medicinal Products.

DOCUMENT REVISION HISTORY

Date of revision	Revision number	Document Number	Author(s)	Changes made and/or reasons for revision
24 Oct. 2019	0	PAR/GDL/020	Mutyaba Michael	First Issue

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